

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aminoven® 8 Solution for Infusion
Aminoven® 16 Solution for Infusion
Aminoven® 25 Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Aminoven is and what it is used for
2. What you need to know before you receive Aminoven
3. How to use Aminoven
4. Possible side effects
5. How to store Aminoven
6. Contents of the pack and other information

1. What Aminoven is and what it is used for

Aminoven provides nourishment straight into your blood stream when you cannot eat normally. It provides amino acids which your body will use to make proteins (to build and repair muscles, organs, and other body structures).

Aminoven is typically mixed in a pharmacy with fat, carbohydrates, salts and vitamins, which together provide your complete nutritional needs.

This leaflet covers 3 products:

- Aminoven 8 Solution for Infusion
- Aminoven 16 Solution for Infusion
- Aminoven 25 Solution for Infusion

In this leaflet the three solutions are collectively referred to as Aminoven.

2. What you need to know before you receive Aminoven

You should not receive Aminoven if you are suffering from, or have suffered from the following.:

Do not use Aminoven:

- if you have a condition where your **body has problems using proteins or amino acids**
- if you have **metabolic acidosis** (the acid levels of your body fluids and tissues become too high)
- if you have reduced **kidney** function and are not on dialysis or another form of blood filtration treatment
- if you have seriously reduced **liver function**
- if you have **fluid retention**
- if you suffer from **shock**
- if you have **hypoxia** (low levels of oxygen)
- if you have a **decompensated heart failure**

Aminoven **8 and 16** should **not be used for children below 2 years** of age.

Aminoven **25%** should **not be used for children and adolescents below 18 years** of age.

For children under 2 years, paediatric amino acid preparations which are formulated to meet their different metabolic needs should be used.

Warnings and precautions

Inform your doctor if you:

- suffer from **low levels of potassium** (hypokalaemia)
- suffer from **low levels of sodium** (hyponatraemia)
- suffer from **folate deficiency**
- suffer from **heart failure** (cardiac insufficiency)

The doctor or nurse will check that the solution is particle free before usage.

Other medicines and Aminoven

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant, if you think you are pregnant or if you are breastfeeding. The doctor will decide if you should receive Aminoven.

Driving and using machines

Aminoven infusion has no effect on driving or using machines.

3. How to use Aminoven

You will receive your medicine by infusion (IV drip).

The amount and rate at which the infusion is given depends on your requirements.

Your doctor will decide on the correct dose for you to receive.

You may be monitored during your treatment.

If you use more Aminoven than you should

It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. The effects of an overdose may include nausea, vomiting and shivering. If you experience these symptoms or believe that you have received too much Aminoven inform your doctor or nurse immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Aminoven can cause side effects, although not everybody gets them.

The following side effects have been observed when infusion was administered too quickly:

- loss of potassium or sodium from the blood
- folate deficiency

At the site of injection the following side effects may occur:

- soreness and tenderness of the vein
- thrombosis (the formation of a clot) in the vein where the injection is given

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

V005

The following information is intended for medical or healthcare professionals only:

Posology and method of administration

The daily requirement of amino acids depends on the body weight and the metabolic conditions of the patient.

The maximum daily dose varies with the clinical condition of the patient and may even change from day to day.

The recommended infusion period is to provide a continuous infusion for at least 14 hours up to 24 hours, depending on the clinical situation. Bolus administration is not recommended.

The solution is administered as long as a parenteral nutrition is required.

Aminoven 8:

For administration via a peripheral or central vein as a continuous infusion.

The usual daily dose Aminoven 8 is 16 - 20 ml of per kg body weight (equivalent to 0.8 - 1.0 g amino acids per kg body weight) e.g. corresponding to 1120 - 1400 ml Aminoven 8 at 70 kg body weight.

Maximum infusion rate is 2.0 ml of Aminoven 8 per kg body weight per hour (equivalent to 0.1 g amino acids per kg body weight and hour).

Maximum daily dose to adults

20 ml of Aminoven 8 per kg body weight/day (equivalent to 1.0 g amino acids per kg body weight) e.g. corresponding to 70 g amino acids at 70 kg body weight. For an increased amino acids dosage suitable preparations are available.

Maximum daily dose to children and adolescents (2-18 years) 40 ml of Aminoven 8 per kg body weight/day (equivalent to 2.0 g amino acids per kg body weight/day) but total daily fluid intake must be considered.

Aminoven 16:

For administration via a central vein as a continuous infusion.

The usual daily dose Aminoven 16 is 10 - 20 ml per kg body weight equivalent to 1.0 - 2.0 g amino acids per kg body weight) e.g. corresponding to 700 - 1400 ml Aminoven 16 at 70 kg body weight.

Maximum daily dose to adults, adolescents and children (from 2 years)

20 ml of Aminoven 16 per kg body weight/day (equivalent to 2.0 g amino acids per kg body weight) e.g. corresponding to 1400 ml Aminoven 16 or 140 g amino acids at 70 kg body weight.

Aminoven 25

For administration via a central vein as a continuous infusion.

The usual daily dose Aminoven 25 is 6.7-13.3ml per kg body weight (equivalent to 1.0-2.0g amino acids per kg body weight) corresponding to 470 to 930ml Aminoven 25 at 70kg body weight.



Ireland

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5. How to store Aminoven

Keep this medicine out of the reach and sight of children. Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Aminoven infusion.

Do not freeze and always keep the container in the outer carton.
The solution must not be used after the expiry date shown on the label.
Any solution remaining after treatment should be disposed of via approved hospital procedures.

6. Contents of the pack and other information

What Aminoven solution for infusion contains

Each 1000 ml of Aminoven contains the following active ingredients:

Active Ingredients	Quantity (g)		
	Aminoven® 8	Aminoven® 16	Aminoven® 25
Isoleucine	2.50	5.00	5.20
Leucine	3.70	7.40	8.90
Lysine acetate	4.655	9.31	15.66
Methionine	2.15	4.30	3.80
Phenylalanine	2.55	5.10	5.50
Threonine	2.20	4.40	8.60
Tryptophan	1.00	2.00	1.60
Valine	3.10	6.20	5.50
Arginine	6.00	12.00	20.00
Histidine	1.50	3.00	7.30
Alanine	7.00	14.00	25.00
Glycine	5.50	11.00	18.50
Proline	5.60	11.20	17.00
Serine	3.25	6.50	9.60
Tyrosine	0.20	0.40	0.40
Taurine	0.50	1.00	2.00

Aminoven 8 and Aminoven 16 also contain glacial acetic acid and water for injections.

Aminoven 25 also contains glacial acetic acid, water for injections and malic acid.

What Aminoven looks like and contents of the pack

Aminoven 8 and Aminoven 16 are available in colourless glass bottles with a rubber closure/aluminium cap that contain 500 ml or 1000 ml of solution.

Aminoven 25 is available in colourless glass bottles with a rubber closure/aluminum cap that contains 250ml, 500ml or 1000ml of solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

MAH for UK:

Fresenius Kabi Ltd., Cestrian Court,
Eastgate Way, Manor Park,
Runcorn, Cheshire, WA7 1NT, U.K.

MAH for IRL:

Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d. Höhe
Germany

Manufacturer

Aminoven in glass bottles is manufactured by:

Fresenius Kabi Austria GmbH
Hafnerstrasse 36
A-8055 Graz
Austria

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Maximum infusion rate is 0.67ml of Aminoven 25 per kg body weight and hour (equivalent to 0.1g amino acids per kg body weight and hour).

Maximum daily dose to adults

13.3ml of Aminoven 25 per kg body weight/day (equivalent to 2.0g amino acids per kg body weight) e.g. corresponding to 140g amino acids at 70kg body weight.

Aminoven 25 is contraindicated in children.
The solution is administered as long as a parenteral nutrition is required.

Overdose (symptoms, emergency procedure, antidotes):

As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when Aminoven is given in overdose or the infusion rate is exceeded.
Infusion should be stopped immediately in this case. It may be possible to continue with a reduced dosage.
A too rapid infusion can cause fluid overload and electrolyte disturbances.
Emergency procedures should be general supportive measures, with particular attention to respiratory and cardiovascular systems. Close biochemical monitoring would be essential and specific abnormalities treated appropriately.
There is no specific antidote for overdose.

Storage

Keep out of the reach and sight of children.
Keep container in the outer carton. Do not store above 25°C. Do not freeze. Use only clear, particle-free solutions and undamaged containers.
Do not use Aminoven after the expiry date which is stated on the label after Expiry Date. The expiry date refers to the last day of that month.
Aminoven should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

Aminoven may be aseptically admixed with other nutrients such as fat emulsions, carbohydrates and electrolytes. Chemical and physical stability data for a number of admixtures stored at 4°C for up to 9 days are available from the manufacturer upon request.

From a microbiological point of view, TPN admixtures compounded in uncontrolled or unvalidated conditions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally be no longer than 24 hours at 2 to 8°C, unless mixing has taken place in controlled and validated aseptic conditions.